

WHAT IS CLAIMED IS:

1. A monoclonal antibody, or binding fragment thereof, which binds specifically to an antigen present in human breast cancer, human lung cancer, and human bladder cancer, the antigen being (i) one or more polypeptides having an apparent molecular weight of about
5 40-52 or 130-200 kDa as determined by SDS-PAGE under reducing conditions; and (ii) absent from human breast, lung and bladder tissue cells.
2. The monoclonal antibody, or binding fragment thereof, according to Claim 1, which is produced by a hybridoma cell line designated 7C8 cell line.
3. The monoclonal antibody or binding fragment thereof, according to Claim 1,
10 wherein the binding fragment is selected from the group consisting of Fab fragments, F(ab)₂ fragments, Fab' fragments, F(ab')₂ fragments, Fd fragments, Fd' fragments and Fv fragments.
4. An anti-idiotypic antibody which mirrors the binding site of the antibody according to Claim 1.
5. A hybridoma cell line which produces a monoclonal antibody which binds
15 specifically to an antigen present in human breast cancer, human colon cancer, human esophagus cancer, human liver cancer, human lung cancer, and human ovary cancer, the antigen being (i) one or more polypeptides having an apparent molecular weight of about 40-52 or 130-200 kDa as determined by SDS-PAGE under reducing conditions; and (ii) it is absent from human breast, colon, lung and bladder tissue cells.
- 20 6. The hybridoma cell line according to Claim 5, which is the cell line 7C8.
7. An antibody-recognized surface antigen present in human breast cancer, human colon cancer, human esophagus cancer, human liver cancer, human lung cancer, and human ovary cancer, the antigen being (i) one or more polypeptides having an apparent molecular weight of about 150 kDa as determined by SDS-PAGE under reducing conditions;
25 and (ii) absent from human breast, lung and bladder tissue cells.

8. The antibody-recognized surface antigen according to Claim 7, wherein the antibody that binds to the antigen is a monoclonal antibody produced by a hybridoma cell line designated as 7C8.

9. A method of inhibiting or killing cancer cells, comprising: providing to a patient in need thereof the monoclonal antibody, or binding fragment thereof, according to Claim 1, under conditions and in an amount sufficient for the binding of the monoclonal antibody, or binding fragment thereof, to the cancer cells, thereby causing inhibition or killing of the cancer cells by the immune cells of the patient.

10. The method according to Claim 9, wherein the cancer is breast cancer, colon cancer, esophagus cancer, liver cancer, lung cancer, or ovary cancer

11. The method according to Claim 9, further wherein the monoclonal antibody is conjugated with a cytotoxic moiety.

12. The method according to Claim 11, wherein the cytotoxic moiety is a chemotherapeutic agent, a photoactivated toxin, or a radioactive agent.

13. The method of Claim 11, wherein the cytotoxic moiety is Ricin A chain.

14. The monoclonal antibody, or binding fragment thereof, according to Claim 1, bound to a solid matrix.

15. A method of localizing cancer cells in a patient, comprising: (a) administering to the patient a detectably-labeled monoclonal antibody, or binding fragment thereof, according to Claim 1; (b) allowing the detectably-labeled monoclonal antibody, or binding fragment thereof, to bind to the cancer cells within the patient; and (c) determining the location of the labeled monoclonal antibody or binding fragment thereof, within the patient.

16. A method of detecting the presence and extent of cancer in a patient, comprising: determining the level of the antigen according to Claim 7 in a sample of bodily fluid or a tissue section from the patient and correlating the quantity of the antigen with the presence and extent of the cancer disease in the patient.

17. The method according to Claim 16, wherein the antigen is detected by (1) adding monoclonal antibody 7C8 to the sample or tissue section; (2) adding goat anti-mouse IgG antibody conjugated with peroxidase; (3) fixing with diaminobenzidine and peroxide, and (4) examining the sample or section, wherein reddish brown color indicates that the cells bear the antigen.

18. A method of monitoring the effectiveness of therapy for cancer disease, comprising: periodically measuring changes in the level of the antigen according to Claim 7 in a body fluid sample taken from a patient undergoing the therapy, and correlating the change in level of the antigen with the effectiveness of the therapy, wherein a lower level of antigen determined at a later time point relative to the level of antigen determined at an earlier time point during the course of therapy indicates effectiveness of the therapy for the cancer disease.

19. The method of Claim 15, wherein the monoclonal antibody is radiolabeled; fluorochemical labeled, or enzyme labeled.

20. The method of Claim 15, wherein the method is an ELISA.

21. A method of diagnosing the presence of cancer in a patient, comprising: (a) measuring the levels of the antigen according to Claim 7 in cells, tissues, or body fluids of the patient; and (b) comparing the measured levels of the antigen of (a) with levels of the antigen in cells, tissues, or body fluids from a normal human control, wherein an increase in the measured levels of the antigen in the patient versus the normal control is associated with the presence of the cancer.

22. A method of imaging cancer in a patient, comprising administering to the patient the antibody according to Claim 1, wherein the antibody is detectably labeled with paramagnetic ions or with a radioisotope.

23. A pharmaceutical composition comprising the monoclonal antibody, or binding fragment thereof, according to Claim 1, and a pharmaceutically acceptable carrier, excipient, or diluent.

24. The monoclonal antibody according to Claim 1, labeled with a detectable moiety.

25. The monoclonal antibody according to Claim 24, wherein the detectable moiety is selected from the group consisting of a fluorophore, a chromophore, a radionuclide, a chemiluminescent agent, a bioluminescent agent and an enzyme.

26. A method for downregulating HER2 receptor levels on an SK-BR-3 cell, comprising contacting the cell with a monoclonal antibody of Claim 1.

27. A method for sensitizing tumor cells to cisplatin or doxorubicin, comprising contacting a monoclonal antibody of Claim 1 to the cell, wherein the antibody specifically binds to the extracellular domain of a HER2 receptor on the cell.

28. A polynucleotide encoding the antigen of Claim 7.

29. A polynucleotide encoding the monoclonal antibody of Claim 1.